Research Ethics in US Medical Education: An Analysis of Ethics Course Syllabi

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Medical education trains future physicians as medical practitioners. For this reason ethics education for medical students has traditionally focused on themes revolving around the patient-physician relationship: veracity, informed consent, fidelity, confidentiality, non-maleficence, and the like (1-3). While many of these themes overlap with themes in research ethics, these ethics courses may be inadequate for those future physicians who will engage in research of any kind – including clinical trials, patient surveys, or program assessments (4-7). Research ethics introduces new and important themes related to experimental design, interaction with communities, and the dissemination of information (8,9). The well being of patients, physicians, and research institutions is at stake when physicians fail to abide by rules for ethical research (9,10).

Recent, highly publicized failures to follow protocol at major medical centers reinforce the idea that Institutional Review Boards (IRBs) are inadequate to ensure ethical research behavior. These facts give rise to an important research question: To what extent is research ethics incorporated into the ethics curriculum at medical schools in the United States (US), where future clinical researchers are trained? This question takes on additional significance when one considers that medical students may be engaged in clinical research in various forms even before completing undergraduate medical studies (5,11,12).

This study builds upon a larger study that the first two authors of this paper conducted on the ethics curriculum in US medical schools. DuBois and Ciesla analyzed syllabi from required ethics courses in US medical schools with the aim of identifying and rank-ordering course objectives, teaching methods, course content, and methods of student assessment (13). (The term “ethics course” is used here to refer broadly either to a self-standing course or to a formal educational unit within a larger course.) The present study analyzes in detail the content of the research ethics portion of required ethics courses in the 4-year medical doctor (MD) curriculum at US medical schools. It makes no attempt to describe responsible conduct of research (RCR) education at medical schools as a whole, which frequently house graduate and postgraduate programs in the biomedical sciences, and accordingly offer more extensive RCR courses outside of their MD programs.

Methods

This study was presented to the Institutional Review Board of Saint Louis University. It was approved

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as an exempt study given guarantees that participation would be voluntary, subjects would be adults, and confidentiality would be maintained by publishing only aggregated data.

Instrument and Participants

The American Association of Medical Colleges (AAMC) provided mailing labels for all curriculum directors of 4-year medical colleges in the US (N=121). A 1-page survey was sent to all curriculum directors asking whether ethics is taught as a formal required component, as an elective, or not at all. It also inquired into the year or years in which ethics is taught. The survey further requested course syllabi for all formal ethics components in the 4-year medical curriculum.

Analysis

In the larger study, two researchers read all syllabi using an open coding method to produce a comprehensive list of all elements found in the syllabi that fell into one of four generic categories: (1) course objectives, (2) teaching methods, (3) course content, and (4) student assessment methods. All other statements (e.g., pertaining to class times, locations, and instructors) were ignored. The specific elements of the syllabi were then placed into categories. These categories were used to create variables in a SPSS database. Schools, rather than syllabi, constituted cases in the database: if a school had more than one required ethics component, data from all required course syllabi were entered into that case. Data from 10 syllabi (17%) were entered by two researchers to establish interrater reliability.

The present study identified those syllabi that included content on research ethics.

The research ethics sections of syllabi were read using an open-coding method to generate a comprehensive list of research ethics content. The results of this open-coding process were then placed into general categories. These categories were entered into an expanded SPSS database. Statistical analysis aimed above all to provide descriptive data on the frequency of various research ethics content. Pearson's r was used to test whether the mean number of content areas covered was significantly correlated with either class size or tuition cost.

Results

Surveys were returned by 72% of the schools (n=87). Seventy-nine percent (n=69) of these schools claimed to require a formal ethics course. Of these schools, 84% (n=58) provided ethics course syllabi. The two raters categorized items the same in 90% of the cases. In the predecessor study, analysis and codification of all syllabi identified 10 course objectives, 8 teaching methods, 39 content areas, and 6 methods of student assessment. The mean for individual schools was 3 objectives, 4 teaching methods, 13 content areas, and 2 methods of assessment.

Among the 39 different content areas, research ethics ranked 11th. Twenty-three of the 58 syllabi (39.6%) addressed research ethics in some fashion. Analysis of the research ethics sections of these syllabi revealed 82 specific themes that fall under 17 different general categories.

Table I (below) presents these 17 general categories in rank order, along with the specific themes that fall under each category. It further indicates where the categories and specific themes overlap with the US Public Health Service's (PHS) "Core Instruction Areas" for courses on the Responsible Conduct of Research (RCR) (14). (This policy of December 1, 2000 was suspended by the Bush administration in February 2001 pending further study. This paper refers to the policy because it continues to serve as a model for many institutions and it remains under discussion among legislators and policy makers.)

The average number of general research ethics topics addressed in these 23 syllabi is 6, with individual schools covering anywhere from 1 to 11 topics. Only six topics were covered by more than half of those syllabi that address research ethics. In rank order these are: clinical trials; informed consent; general ethics of human subject research; government committees and regulations; history and background to research ethics; and protecting vulnerable populations. No research ethics topic was covered by more than 21% of the 87 participating schools. The number of research ethics topics covered did not correlate significantly with either school enrollment ($r=.10$, $p<.45$) or tuition costs ($r=.10$, $p<.43$).

Discussion

While Mastroianni and Kahn conducted a useful and informative pilot study of NIH grantee institutions' training efforts in RCR, this study is the first to examine comprehensively the RCR curriculum in US medical programs. Our study

exposes two possible causes for concern. First, too few medical schools teach research ethics in any fashion within their MD program. No topic in research ethics – including clinical trials – is covered by more than 21% of all medical schools. The topic of Institutional Review Boards is covered by less than 13% of medical schools, despite the fact that medical researchers are most likely to work precisely with human subjects. Second, it appears that important topics are wholly missing even in those programs that teach research ethics. This becomes clear when comparing the specific research ethics topics covered within medical ethics syllabi to the "Core Instruction Areas" PHS identified for RCR education (14). For example, the first five of nine core areas PHS identifies (data acquisition, management, sharing, and ownership; mentor / trainee responsibilities; publication practices and responsible authorship; peer review; and collaborative science) seem wholly missing from these syllabi. (The only possible exception is one syllabus that mentions industry/university relationships.)

It is, of course, possible that some of these topics are covered under other general headings (e.g. 'collaborative research' might be discussed under 'clinical trials'). This is one limitation of the method used: a topic is identified only if it explicitly appears on the course syllabus. This means that syllabi using only very general headings will be shortchanged. Nevertheless, a course syllabus should be a reliable statement of the objectives and content of a course, and most syllabi were quite detailed (as the larger study demonstrated). Thus, it seems safe to conclude both that very few MD programs discuss research ethics and that those that do ignore at least half of the topics PHS wants to see addressed.

However, the significance of these findings cannot be firmly established until other questions are answered:

- To what extent are medical students participating in clinical research?
- Are current requirements for RCR instruction likely to be successful in targeting future physicians who are funded by private industry?
- To what extent do clinical researchers encounter special ethical topics that are not covered in general RCR courses?

These questions remain unanswered. Literature in academic medicine has addressed the roles of undergraduate medical students in research (5,11,12). However, the prevalence and extent of students' roles and whether they are specifically listed in study protocols remains unknown. Thus, it is difficult to know whether education in RCR is a pressing need for medical students, or whether these years might be viewed simply as a convenient time to introduce education in RCR.

Research has shown that private industry is now funding more research than is the government (15). Government requirements regarding RCR instruction pertain only to government-funded research, and according to at least one study, two-thirds of NIH grantee institutions require RCR instruction only to the extent that the government mandates it (16). These facts suggest that a "blanket" approach to educating future physicians would be the safest route to ensuring RCR instruction for clinical researchers. However, given the scope of recent government requirements, such a blanket approach would have to be initiated by a professional institution like the AAMC.

Finally, it is difficult to anticipate how well the RCR programs that are currently being mandated will address the specific ethical concerns that arise in clinical, medical research. This study has shown that 13 of our 17 categories could easily be subsumed under just one PHS Core Area: #6, Human Subjects. This suggests that typical RCR instruction aims to cover a broad range of issues that arise in research (such as authorship, peer review and the treatment of animals), whereas physicians feel the need for a highly focused and intensive treatment of human subject research. The years of medical school may be the best or only time to provide this sort of special-tailored education in RCR.

While this study has provided new answers to questions about the current educational training of medical students in RCR, it has also managed to bring new questions to the fore. Only after these questions are answered, will the significance of this study's findings be properly understood.

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Table I: Rank Order and Content of the Research Ethics Categories

*An **asterisk *** followed by a number indicates that the general category or specific topic overlaps with a PHS Policy "Core Instructional Area." The number indicates which of nine instructional areas it overlaps with.*
***'Percent valid'** indicates how often a research ethics topic is included in those syllabi from the 23 schools that actually teach research ethics.*
***'Percent all'** indicates how often a research ethics topic is included among all participating schools (i.e., the 87 schools that returned a survey).*

1. CLINICAL TRIALS (*6) – 78% of valid / 21% of all
   - Therapeutic vs. non-therapeutic research
   - Person as patient vs. research subject
   - Physician as clinician vs. physician as scientist
   - Selection of subjects for clinical trials
   - Randomization
   - Patient as research subject vs. health research subject
   - Ethics of medical students' roles in clinical research
   - Drug testing and the role of the FDA
   - Whether scientific methods provides sole criterion for treatment efficacy
   - Industry / university relationships (*possibly 5 & 9)
   - Types of clinical trials
2. INFORMED CONSENT (*6) – 70% of valid / 18% of all
   - Informed consent in clinical vs. research setting
   - Sample consent form for adults
   - Emergency waiver of informed consent
   - Coercion
   - Deception – active and passive
   - Placebos
3. GENERAL ETHICS OF HUMAN SUBJECT RESEARCH (*6) – 65% of valid / 17% of all
   - Ethics of human experimentation
   - Justification of research involving human subject
   - Challenges to human subject protections
4. GOVERNMENT COMMITTEES & REGULATIONS (*6 & others) – 61% of valid / 16% of all
   - Belmont report
   - President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1979-83)
   - National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78) [Published Belmont Report]
   - Federal regulations
   - National Bioethics Advisory Committee
   - Declaration of Helsinki
   - Practice and regulations
   - OPRR reports, Protection of Human Subjects
   - Title 45, Code of Federal Regulations, part 46 (1994)
   - Nuremberg Code (as living document)
5. HISTORY AND BACKGROUND OF RESEARCH ETHICS – 57% of valid / 15% of all
   - Nazi experimentation / Holocaust (awareness of attitudes toward)
   - Nuremberg Code (as historical document)
   - Tuskegee study of syphilis (awareness and attitudes toward)
   - Abuses and errors of early eugenics
   - "Frankenstein"
   - Sloan-Kettering experiments
   - Willowbrook experiments
   - Henry Beecher revisited (article by DJ Rothman)
   - Introduction to sulfonamides revisited (articles by BH Lerner)
   - Research in the Hippocratic Oath (i.e., the fact that it is not addressed therein)

6. PROTECTING VULNERABLE POPULATIONS (*6) – 52% of valid / 14% of all
   - Minorities
   - Newborns, Infants, Children
   - Soldiers
   - Prisoners
   - Mentally ill
   - AIDS patients
7. IRB (*6) – 48% of valid / 13% of all
   - IRB issues
   - Definition of research / Novel therapy vs. research
8. RESEARCH INTEGRITY & MISCONDUCT (*8 & 9) – 39% of valid / 10% of all
   - Accuracy of published data
   - Research fraud (*8)
   - Appearance of impropriety
   - Scientific misconduct (*8)
   - Scientific integrity
   - Appropriate credentials
   - Research quality guidelines for both academic and non-academic environments
   - Conflicts of interest (*9)
9. ETHICAL PRINCIPLES IN HUMAN SUBJECT RESEARCH (*6) – 39% of valid / 10% of all
   - Respect autonomy
   - Do good (beneficence)
   - Fairness / justice
   - Avoid harm to subjects (non-maleficence)
   - Justify level of risk
   - Apply process of ethical decision making to research ethics
10. ANIMAL EXPERIMENTATION (*7) – 30% of valid / 8% of all
    - Animal rights
    - Use of animals for research
    - Poor living conditions for research animals
11. GENETIC RESEARCH AND THERAPY (*6) – 26% of valid / 7% of all
    - Genetic research
    - Germ-line therapy
    - Somatic cell genetic therapy
    - National Human Genome Research Institute
    - Genetic information and privacy
    - Cystic fibrosis research
12. RESEARCH AND THE SOCIAL GOOD (*6) – 22% of valid / 6% of all
    - Medicine and the goals of society
    - Research in the international context
    - Social utility of research
    - Relationship between ethics, science, and technology
    - Balancing society's mandates, competing pressures to innovate
13. MINIMIZING RISKS (*6) – 22% of valid / 6% of all
    - Establishing gold standard
    - Asking whether risk is proportionate to benefit
14. SUBJECT SELECTION (*6) – 13% of valid / 3% of all
    - Ensuring the inclusion of women, children and minorities (a concern of justice, rather than protection)
15. EMBRYO AND FETAL RESEARCH (*6) – 9% of valid / 2% of all
    - Stem cell research
    - Research on live-born fetuses
16. EPIDEMIOLOGY (*6) – 4% of valid / 1% of all
    - Ethics of epidemiology
17. MILITARY RESEARCH ETHICS (*6) – 4% of valid / 1% of all
    - Experiments related to weaponry
    - Using compounds not fully tested in a wartime situation